

ISIC-0001-103 (ISIS-4945)

PATENT

REMARKS

Applicants' amendment and remarks filed May 12, 2003 are represented herein.

Regretfully, Applicant's responses to the rejections under 35 U.S.C. § 112 were inadvertently omitted from the prior response, and are now presented herein.

After entry of the present amendment, claims 31-42 will be pending. Support for the new claims can be found in the claims as originally filed.

Claims 1, 3, 8-12 and 14-15 are rejected under 35 U.S.C. § 102(e) for alleged anticipation by U.S. Patent No. 5,843,738 to Bennett et al (hereinafter "Bennett 738"). These claims have been canceled herein by Applicants solely to advance prosecution of this application, thus technically rendering the rejection moot. Nevertheless, Applicants respectfully point out that Bennett 738 does not disclose (or suggest) the use of enema formulations comprising the antisense oligonucleotide of SEQ ID NO: 1, as is recited in the present claims. Accordingly, Applicants believe the present claims to be patentable over this reference, and therefore request withdrawal of the rejection.

Claims 1-15 and 32 are rejected under 35 U.S.C. § 102(e) for alleged anticipation by U.S. Patent No. 6,096,722 to Bennett et al. (hereinafter "Bennett 722"). These claims also have been canceled herein by Applicants solely to advance prosecution of this application, thus also technically rendering this rejection moot. Nevertheless, Applicants respectfully point out that the Bennett 722 reference is not properly applied against the present claims. The Bennett 722 reference has a filing date of May 27, 1998, whereas the present application claims benefit of prior application Ser. No. 09/082,624 ("the 624 application"), which was filed May 21, 1998.¹ The 624 priority application discloses enema formulations comprising an oligonucleotide of SEQ ID NO: 1, at, for example page 81. Thus, the Bennett 722 reference is not properly applied against the claims as amended. Accordingly, Applicants respectfully request withdrawal of the rejection.

¹ Both the declaration filed by Applicants on May 3, 2002, in connection with the 624 application, and the filing receipt of the 624 application, list the filing date as May 31, 1998. This typographical error is currently being corrected by Applicants. Copies of the return postcard evidencing mailing of the 624 application to the Office on May 21, 1998 is provided herewith for the Examiner's convenience.

ISIC-0001-103 (ISIS-4945)**PATENT**

Claims 27-29 are rejected under 35 U.S.C. §102(e) for alleged anticipation by U.S. Patent No. 5,877,162 to Werner et al. (hereinafter "Werner"). Inasmuch as the Werner reference does not disclose or suggest enema oligonucleotide formulations comprising oligonucleotides of SEQ ID NO:1, the present claims are not anticipated by this reference. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim 30 is rejected under 35 U.S.C. §102(c) for alleged anticipation by U.S. Patent No. 5,846,525 to Manair et al. (hereinafter "Manair"). Inasmuch as the Manair reference does not disclose or suggest enema oligonucleotide formulations comprising oligonucleotides of SEQ ID NO:1, the present claims are not anticipated by this reference. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claims 12-13, 28 and 31 are rejected under 35 U.S.C. §112, second paragraph, for lack of antecedent basis for claim terms, and for the improper recitation of the name "lipofectin". Claims 12-13, 28 and 31 have been cancelled, thus rendering the rejection moot. In addition, it is believed that the new claims address the concerns of the Office Action. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claims 9 and 10 are rejected under 35 U.S.C. §112, first paragraph, for lack of enablement, on the basis that the specification does not provide a sufficient written description. Specifically, the Office Action asserts that the present specification does not describe a sufficient number of representative species of antisense oligonucleotides to show that Applicants had possession of the claimed invention. While these claims have been cancelled solely to advance prosecution, thus rendering the rejection moot, Applicants nevertheless respectfully disagree with the Office Action, and assert that the formerly pending claims are fully enabled. The Office Action admits that the specification discloses "several representative antisense oligonucleotides" encompassed by the claims that "target various cell adhesion proteins", but nevertheless asserts that "the structure of these antisense oligonucleotides does not allow one of skill in the art to predict the structures of the full scope of antisense compounds encompassed by the claimed invention..." Office Action at page 7. Thus, as best understood, the Office Action appears to reject claims 9 and 10 because they contain functional limitations. However, as will be

ISIC-0001-103 (ISIS-4945)

PATENT

recognized, the enablement requirement of §112 is satisfied so long as a disclosure contains sufficient information that persons of ordinary skill in the art having the disclosure before them would be able to make and use the invention. *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988) (the legal standard for enablement under §112 is whether one skilled in the art would be able to practice the invention without undue experimentation). Moreover, it is well established that a composition may be claimed using functional language or in terms of its properties. *In re Swinehart*, 169 U.S.P.Q. 226, 228 (C.C.P.A. 1971). Thus, Applicants are not required to set forth structures of numerous antisense oligonucleotides within the scope of the claims. Rather, Applicants are required to teach persons of ordinary skill in the art having the disclosure before them would be able to make and use the invention without undue experimentation. As those of skill in the art would undoubtedly be able to do so from the present specification, former claims 9 and 10 are fully enabled.

Applicants assert that the claims are in condition for allowance, and respectfully request notification to that effect. Should the Office have any questions, Applicants invite the Office to contact the undersigned at (215) 665-5548 to discuss any issued unresolved by this Supplemental Amendment. A Notice of Allowance is earnestly solicited.

Respectfully submitted,



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